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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SCHELL, LAURA C	

ART UNIT	PAPER NUMBER
3767	

NOTIFICATION DATE	DELIVERY MODE
01/07/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No.	Applicant(s)	
	10/063,159	AKERLUND ET AL.	
	Examiner	Art Unit	
	LAURA C. SCHELL	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13,15,17-21,23-26 and 28-49* is/are pending in the application.

4a) Of the above claim(s) *2,4-7,11,18,23-25,29 and 34-49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,10,12,13,15,17,19-21,26,28,30-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 October 2009* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

The amendment filed 10/23/2009 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the addition of element 107 to the amendment made to Fig. 5 is being considered new matter as there is no support in the specification for the fluid bag with a internally held spike in the inlet port having a fluid barrier. Furthermore, the originally filed Fig. 5 lacks this feature and the specification is does not discuss that element 107 which is present in the originally filed Fig. 1 can be used within other embodiments of the device.

The examiner has reviewed the claims, particularly the portion of claim 3 in which it recites “wherein said fluid barrier is provided inside said second fluid duct”. This indicates that the fluid barrier is only located within the fluid duct in the cap, labeled as 309 in Fig. 5. This is also supported by the fact that the originally filed Fig. 5 includes 309 as a reference numeral.

Therefore it appears that the specification nor the originally filed drawings have support for a fluid barrier in the inlet port containing the hollow spike member.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 recites the limitation "said second fluid duct" in the last line of claim 21. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1, 8, 10, 12, 16, 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Scarrow (US Patent No. 5,061,264). Scarrow discloses: a fluid transfer assembly (Fig. 1) for use in an infusion system, said assembly comprising: a fluid container (10) having an infusion fluid, a drug container (48) having a medical substance, at least one fluid barrier (74 and 14) controlling fluid passage between said drug container and said fluid container, said fluid container further comprising at least one inlet port (the inlet port is being interpreted as the portion between the walls of the fluid container which surround 12. Please note that Applicant has not claimed any

structure regarding the inlet port) for receiving said medical substance from said drug container, a hollow spike member (Fig. 1, 12) arranged to be retained inside walls of said inlet port (the walls of the inlet port are the walls of the fluid container packaging that surround and hold 12 in place) and provided with a first luer-lock connector (16), said drug container further comprising a cap (20) for sealing said drug container, said cap further comprising a second luer lock connector (32; col. 3, lines 37-38 disclose that portion 32 is the connector that connects with luer lock connector 16) for attachment to said first luer lock connector, wherein said at least one fluid barrier is designed and arranged to be ruptured by an external force to allow said fluid passage (col. 3, line 27; col. 4, lines 41-42. Please note that Applicant has not directed in the claim what the force is external relative to. For example, the examiner could interpret the external force as being a force created by pushing the container onto 70 which causes 74, and the force of pushing the container is external relative to the container.).

In reference to claim 8, Scarrow discloses that the second luer lock connector further comprises a pierceable closure (72) for protection before use.

In reference to claim 10, Scarrow discloses that the drug container further comprises an opening sealed by a closure (60), and said cap further comprising a hollow needle (70) for penetrating said closure.

In reference to claim 12, Scarrow discloses that the drug container further comprises a neck (58), said cap further comprising a protruding member (28) forming a second fluid duct between said drug container and said second luer-lock connector, and said cap further comprising locking members (fig. 10 discloses locking members 140

and 141 work together to grasp the neck; also see col. 5, line 60 through col. 6, line 3) for grasping said neck.

In reference to claim 16, Scarrow discloses that the fluid container further comprises a protruding resilient tube (12 protrudes externally from the inside of the fluid container), said first luer lock connector (16) of said at least one inlet port being provided on a hollow spike member (spike part of 14) able to be firmly retained inside said tube.

In reference to claim 20, Scarrow discloses that the composition of said drug container is selected from the group consisting of glass and a rigid polymer material (col. 3, line 65 discloses the drug container is glass).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 21, 26, 28, 30, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scarrow (US Patent No. 5,061,264) in view of Shemesh et al. (US Patent No. 5,817,083). Scarrow discloses a drug container (48) comprising: a fixed dose of a medical substance, and a cap (20) for sealing said drug container (Fig. 1 discloses that the cap is perfectly capable of sealing the drug container), said cap further comprising a luer lock connector (32; col. 3, lines 37-38 disclose that portion 32 is the connector that connects with luer lock connector 16) for attachment to a corresponding connector (16) provided on a hollow spike that is arranged to be retained inside walls of an inlet port of a container for infusion fluid (Fig. 1, spike 12 has luer connector 16, the spike is held within the walls of the inlet portion (which is the portion of the bad surrounding the spike 12)), thereby creating a luer lock coupling (16 and 32/36 form a luer lock coupling), said cap further comprising a protruding member forming a fluid duct between said drug container and said second luer-lock connector (28 protrudes from the cap and forms a fluid conduit between the drug container and the second luer lock) and a fluid barrier able to be ruptured by an external force (barrier 74 is able to be ruptured by an external force; col. 4, lines 41-42. Please note that "external force" is a rather broad limitation as there is no indication in the claim indicating what the force is external relative to (a force that is external relative to the drug container, for example). Scarrow, however, does not disclose that the fluid barrier is provided inside the second conduit. Shemesh, however, discloses a similar device (Fig. 1) in which a cap (16) includes an extension (14) which can attach to the port of the bag (attach at port 10) and Shemesh further discloses a rupturable barrier (32) that

is located within fluid conduit, that when broken/ruptured allows fluid to flow between the bad and the drug container. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Scarrow's conduit to include an internal fluid barrier, as taught by Shemesh, as this would allow the user to selectively allow fluid flow when desired and the internal barrier allows the barrier to remain sterile.

In reference to claim 26, Scarrow discloses a pierceable closure (72) for protecting said second luer lock connector (72 is perfectly capable of protecting the luer lock connector (32) from anything that may enter from the open end of 46).

In reference to claim 28, Scarrow discloses that the drug container further comprise an opening sealed by a closure (60), and said cap further comprises a hollow needle (70) for penetrating said closure.

In reference to claim 30, Scarrow discloses that the drug container further comprises a neck (58), said cap further comprises a protruding member (28) forming a second fluid duct between said drug container and said second luer lock connector, and said cap further comprising locking members (locking members 140 and 141 work together to grasp the neck of the drug container; also see col. 5, line 60 through col. 6, line 3) for grasping said neck.

In reference to claim 32, Scarrow discloses that the cap further comprises a protruding member (28) forming a fluid duct between said drug container and said luer lock connector, wherein a fluid barrier is provided inside said fluid duct (rupturable barrier 74 is within 28, as 28 extends all the way into the cap portion to where 74 is

located), said drug container comprising a rigid material (col. 3, line 65 discloses the drug container is glass), said protruding member comprising a more flexible material than said luer lock connector and said drug container, and said fluid barrier is made of a more brittle material than said drug container (col. 4, lines 41-42)., said protruding portion, and said luer lock connector.

In reference to claim 33, Scarrow discloses that the drug container is made from glass (col. 3, line 65).

Claims 3 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scarrow (US Patent No. 5,061,264) in view of Shemesh et al. (US Patent No. 5,817,083). Scarrow discloses the device substantially as claimed including the cap having a protruding member forming a second fluid duct between the drug container and the second luer-lock connector (Fig. 1, 28), however Scarrow does not disclose that the fluid barrier is provided inside the second conduit. Shemesh, however, discloses a similar device (Fig. 1) in which a cap (16) includes an extension (14) which can attach to the port of the bag (attach at port 10) and Shemesh further discloses a rupturable barrier (32) that is located within fluid conduit, that when broken/ruptured allows fluid to flow between the bad and the drug container. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Scarrow's conduit to include an internal fluid barrier, as taught by Shemesh, as this would allow

the user to selectively allow fluid flow when desired and the internal barrier allows the barrier to remain sterile.

Claims 13 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scarrow (US Patent No. 5,061,264) in view of Shemesh et al. (US Patent No. 5,817,083) and further in view of Haber et al. (US Patent No. 5,593,028). Scarrow in view of Shemesh discloses the device substantially as claimed including a fluid barrier (74), however, Scarrow does not disclose that the barrier is a brittle polymer. Haber, however, discloses a rupturable barrier comprises of a brittle polymer dividable along a weakening line by said external force (col. 7, lines 5-16). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Scarrow in view of Shemesh with the brittle barrier, as taught by Haber, in order to provide a barrier that is assured to break upon the external force applied, in order to assure that the flow between containers takes place during a critical medical infusion to a patient.

Claims 15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scarrow (US Patent No. 5,061,264) in view of Shemesh et al. (US Patent No. 5,817,083) and further in view of Vaillancourt (US Patent No. 5,897,526). Scarrow in view of Shemesh discloses the device substantially as claimed including a protruding

member (28) forming a second fluid duct between said drug container and said second luer lock connector and an inlet port (12). However, Scarrow in view of Shemesh does not disclose a clamping members or an infusion line. Vaillancourt, however, discloses a clamping members (Fig. 14, 22' and 55) as well as an infusion line (12) attached to the inlet port. The clamping members could be used on the neck portion of (28) to compress the protruding member, thereby closing said second fluid duct and preventing undesirable fluid passage between said second luer lock connector and said drug container, and the infusion line could be used at the inlet port to allow the medication/fluid to be infused into the patient. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Scarrow in view of Shemesh with the clamping member and infusion line, as taught by Vaillancourt, in order to provide a means for delivering the medication as well as to provide a means for stopping flow in the even that flow between the drug container and the fluid container needs to be suddenly stopped.

Response to Arguments

Applicant's arguments with respect to claims 1, 3, 8, 10, 12, 13, 15, 17, 19-21, 26, 28 and 30-33 have been considered but are moot in view of the new ground(s) of rejection.

The examiner, while applying new rejections above, has maintained the Scarrow and Shemesh references, and it is the examiner's position that Scarrow teaches the device as claimed except for a rupturable barrier internal to the cap's fluid conduit. It is

the examiner's position that Shemesh teaches this feature and it would have been obvious to modify Scarrow's conduit to include this feature. It is also the examiner's position that as the claims are currently worded, the "external force" is broad and does not indicate what the force is external to, and therefore is still taught by the Scarrow and Shemesh references.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA C. SCHELL whose telephone number is (571)272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura C Schell/
Examiner, Art Unit 3767

/Nicholas D Lucchesi/
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